NOV 2 2 2002

510(k) Summary

K023760

Date:	October 31, 2002
Submitter's Name:	Toshiba America Medical Systems, Inc.
Submitter's Address:	P.O. Box 2068, 2441 Michelle Drive, Tustin, CA 92781-2068
Submitter's Contact:	Paul Biggins, Regulatory Affairs Manager (714) 730-5000
Establishment Registration Number:	2020563
Device Proprietary Name:	CT Cardiac Function Analysis Software CSCF-001A, CSCF-001B
Common Name:	Scanner, Computed Tomography, X-Ray [Fed. Reg. No. 892.1750, Pro. Code: 90JAK]
Regulatory Class:	II (per 21 CFR 892.1750)
Performance Standard:	21 CFR Subchapter J, Federal Diagnostic X-ray Equipment Standard
Predicate Device(s):	General Electric CardIQ Function [K013422]
Reason For Submission	new device (software package)

Description of this Device:

The Cardiac Function Analysis software is used to post-process cardiac CT images on the display console of the CT system. Using these post-processed images various measurements can be initiated by the user to obtain clinically relevant information pertaining to the heart. Additionally this information can be used in the detection of cardiovascular disease diagnosis and risk management. Support functions are:

- Generation of Multi-Planar Reconstructed images based upon ECG gated data.
- Manual or semi-automatic contour detection of the ventricular heartwalls.
- Measure and display ventricular wall motions, wall thickness, myocardium mass, ventricle volume and ejection fraction.
- Various data outputs can be selected by the user to generate reports of the above measurements.

Summary of Intended Uses:

The Cardiac Function Analysis (CFA) is a software package that can be used in conjunction with CT cardiac images to semi-automatically calculate and display various Left Ventricular and Right Ventricular functional parameters such as End Systolic and End Diastolic volumes, stroke volume, LV ejection fraction to include peak filling and ejection rates, Myocardial Mass calculations, regional wall motion display and analysis. When interpreted by a trained physician, the software aids in the assessment and in determination of cardiovascular disease diagnosis and management.

Technological Characteristics:

This package is similar in uses and applications as those of the predicate devices. The main difference is in the method used to obtain the final results. Both this and the predicate devices are used as post-processing software to images collected by the parent CT Scanner.

Safety and Effectiveness Concerns:

This device is designed and manufactured under the Quality System Regulations as outlined in 21 CFR § 820. All requirements of the Federal Diagnostic Equipment Standard, as outlined in 21 CFR § 1020.30 and 1020.33, that apply to this upgrade, will be met and reported via a supplement to the initial report for the predicate device. Additionally this system is in conformance with the applicable parts of the IEC-60601 - Medical Device Safety standards.

Substantial Equivalence:

CT Cardiac Function Analysis Software (CFA), Model Numbers CSCF-001A, CSCF-001B is substantially equivalent to the predicate device. This package, and the predicate device, are both post-processing analysis software packages that allow the user to obtain clinically relevant anatomical and functional information from CT images of the cardiac region.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 2 2002

Toshiba America
Medical Systems, Inc.
% Mr. Mark Job
510(K) Program Manager
TÜV Product Service
1775 Old Highway 8, Suite 104
NEW BRIGHTON MN 55112-1891

Re: K023760
Trade/Device Name: Model CGCF-001A/CSCF-001B
Cardiac Function Analysis Software
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography
x-ray system
Regulatory Class: II
Product Code: 90 JAK
Dated: November 7, 2002
Received: November 8, 2002

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K023760

Device Name: Cardiac Function Analysis; Model Number CSCF-001A/CSCF-001B

Indications for Use:

The Cardiac Function Analysis (CFA) is a software package that can be used in conjunction with CT cardiac images to semi-automatically calculate and display various Left Ventricular and Right Ventricular functional parameters such as End Systolic and End Diastolic volumes, stroke volume, LV ejection fraction to include peak filling and ejection rates, Myocardial Mass calculations, regional wall motion display and analysis. When interpreted by a trained physician, the software aids in the assessment and in determination of cardiovascular disease diagnosis and management.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use V OR Over-The-Counter Use _____
(Per 21 CFR 801.109)
(Optional Format 1-2-96)

David A. Lagomarsino
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K023760